SALIVA TEST SPECIFICATIONS

Testosterone

Clinical Information

In men, levels of testosterone begin to decline with age, usually beginning around the mid-40s. In the Hypogonadism in Males (HIM) study, hypogonadism, determined by low testosterone levels and symptoms of androgen deficiency, was diagnosed in 38.7% of men over 45 years old. The decline in testosterone production by the testes can be more precipitous in some men than others. Excessive weight gain, stress, lack of exercise, and many medications can further reduce testosterone levels, leading to symptoms that include low libido, irritability, depression, loss of muscle mass and strength, weight gain, erectile dysfunction, osteoporosis, and adverse changes in the blood lipid profile.

In women, high testosterone, often caused by ovarian cysts, leads to conditions such as excessive facial and body hair, acne, and oily skin and hair. Low testosterone in postmenopausal women, seen particularly after surgical removal of the ovaries, leads to female symptoms of androgen deficiency including loss of libido, thinning skin, vaginal dryness, and loss of bone and muscle mass.

The saliva testosterone reference range in men is 44—148 pg/mL (age-dependent) and for women 16—55 pg/mL.
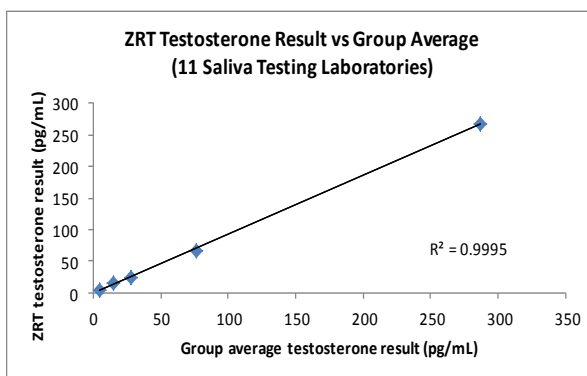
References:

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Arregger AL, Contreras LN, Tumilasci OR, et al. Salivary testosterone: a reliable approach to the diagnosis of male hypogonadism. Clin Endocrinol (Oxf). 2007;67:656-62.

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Assay Method: LIA

Accuracy

ZRT has established the first salivary proficiency testing program, which includes most of the major saliva testing laboratories in the US. Twice yearly, results from carefully selected pooled samples are compared to those from 10 other laboratories that test testosterone. As shown in the graph below, ZRT results compare very favorably to the consensus of all 11 saliva testing laboratories for the testosterone assay.

ZRT Testosterone Result vs Group Average (11 Saliva Testing Laboratories). $R^2 = 0.9995$

Precision/Reproducibility

Inter-assay precision was determined by choosing pooled saliva samples spanning the reference range for testosterone, and analyzing them multiple times over a 30-60 day period. Results are shown below:

Mean Testosterone Concentration (pg/mL)	Coefficient of Variation (C.V. %)
16.3	10.9
30.3	10.2
529.0	14.6

Linearity

The ZRT saliva testosterone assay gives excellent linearity over the reportable range of 5.0-3333.3 pg/mL. Samples giving values >3,333.3 pg/mL are diluted and re-assayed for accurate reporting. Values below 5 pg/mL are not sufficiently precise and are reported as <5 pg/mL.

Sensitivity

The analytical limit of detection for testosterone is 2.1 pg/mL.

Stability

Saliva samples are stable at room temperature for 30 days for testosterone determination, but customers are advised to mail samples as soon as possible after collection. Samples are rejected for analysis if they were not received within 30 days of collection and were not refrigerated or frozen.

Accreditation

ZRT Laboratory is a CLIA and New York State certified testing laboratory.